SECTION 1 THE FSIS NATIONAL RESIDUE PROGRAM

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The regulatory system that enforces the U.S. food safety laws has been evolving since 1906. This system helps to protect the public from foodborne hazards and has enabled the food produced in the U.S. to be among the safest in the world. Nevertheless, maintaining the wholesomeness and safety of the food supply requires continued vigilance and the flexibility to adapt to changing conditions.

On July 25, 1996, the U. S. Department of Agriculture published the Final Rule on Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems. The principal focus of this rule, which complements existing food safety laws and regulations, is to reduce both the pathogenic organisms on meat and poultry products and the incidence of foodborne illness associated with these products. The presence in food of chemical residues above permitted levels causes the food to be adulterated under the Federal Food, Drug, and Cosmetic Act (FFDCA). Under the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), and the Egg Products Inspection Act (EPIA), slaughter and production establishments bear responsibility for ensuring that their product is not adulterated when it enters commerce. Part 417 of the HACCP rule requires meat and poultry establishments to develop and implement a system of preventive measures designed to ensure the safety of their products. In developing their HACCP plans, slaughter establishments must address all chemical, physical, and biological hazards that are reasonably likely to occur in the animals that enter their plants. Section 417.2 requires that slaughter establishments conduct a hazard analysis to determine the food safety hazards reasonably likely to occur before, during, and after entry into the establishment. The preamble of the rule describes the potential hazards that plants need to consider during a hazard analysis. These hazards include chemical residues resulting from use of or exposure to animal drugs, pesticides and environmental contaminants. The rule also provides a new framework for the modernization of the meat and poultry inspection system.

Evidence exists that human illnesses such as allergic reactions, hypersensitivity, and toxicity have resulted from drug residues in animal tissues. Similarly, violative levels of pesticide residues are known to have adverse health effects. Expanding scientific evidence demonstrates that antimicrobial-resistant bacteria may result from both subtherapeutic and therapeutic use of antimicrobial drugs in food animals, and that these antimicrobial-resistant bacteria may subsequently be transmitted from animals to humans through the food chain. A vigilant chemical residue prevention program is essential to fostering the prudent use of drugs and pesticides in animals that enter the human food supply. The requirement that slaughter establishments implement HACCP systems is a significant step in this evolutionary process.

HACCP implementation does not remove or diminish the regulatory authority of FSIS. FSIS inspectors will continue to condemn animals for cause, and FSIS will continue to cooperate with the Food and Drug Administration (FDA) and/or the Environmental Protection Agency (EPA) as a part of follow-ups to residue violations. Any tissue containing a residue that exceeds its

Emergence of Multidrug-Resistant *Salmonella enterica* Serotype *Typhimurim* DT104 Infections in the United States: M. K. Glynn, et al, *The New England Journal of Medicine*: May 7, **1998**, Volume 338, Number 19.

specified tolerance or action level, or that contains a residue that has been banned from use in food animals, is considered to be in violation of FFDCA.

When violative residues are detected in food-producing animals submitted for slaughter, FSIS notifies the producer and any parties involved in offering these animals for sale. These parties are subject to follow-up enforcement testing until compliance is demonstrated. Product found to contain violative levels of residues is considered adulterated and is subject to condemnation. If the product has been distributed into commerce, it may be subject to market recall. In addition, FDA and cooperating state agencies may make on-site visits to these firms. Typically, an educational visit by the state is the first step in attempting to correct a residue problem. If the problem is not corrected, subsequent visits, made by FDA, could result in enforcement action, including prosecution.

FSIS enforces the tolerances and action levels set by FDA and EPA. FDA has statutory authority for setting tolerances and/or action levels for veterinary drugs under the FFDCA, as codified under 21 CFR Part 556 and 109. EPA has statutory authority for setting tolerances and/or action levels for pesticides under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and FFDCA, as modified by FQPA; codified under 40 CFR. Chemical hazards also may be associated with substances that occur in meat, poultry, and egg products as a result of environmental contamination. EPA reviews exposure and toxicology data and may make recommendations to FDA and FSIS on the appropriate action levels for canceled pesticides and other environmental contaminants present in the environment.

The cornerstone of FSIS residue prevention activities is the FSIS National Residue Program (NRP), a multi-component analytical testing program for residues in domestic and imported meat, poultry, and egg products.² The NRP provides a variety of sampling plans to verify that slaughter establishments are fulfilling their responsibilities under HACCP for preventing violative residues and develops national data for chemical residues to support risk assessment, enforcement and educational activities. The range of chemical compounds considered for inclusion in the various NRP testing programs is comprehensive in scope. It includes approved and unapproved pharmaceutical drugs and pesticides known or suspected to be present in food animals in the U.S. and in countries exporting products to the U.S. It also includes any other xenobiotic or naturally occurring compounds that may appear in meat, poultry and egg products and that may pose a potential human health hazard.

The prevention of illegal chemical residues in the food supply is an integral aspect of maintaining a high level of food safety. High consumer expectations necessitate that the U.S. thoroughly document the safety of our meat, poultry, and egg products. In addition, issues related to chemical residues in food may hinder the export of U.S. food products.

The NRP is designed to provide: (1) a structured process for identifying and evaluating compounds of concern by production class; (2) the capability to analyze for compounds of concern; (3) appropriate regulatory follow-up of reports of violative tissue residues; and (4) collection, statistical analysis, and reporting of the results of these activities.

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²The production classes for which FSIS has regulatory authority are: horses, bulls, beef cows, dairy cows, heifers, steers, bob veal calves, formula-fed veal, non-formula-fed veal, heavy calves, sheep, lambs, goats, market hogs (including roaster pigs), boars/stags, sows, young chickens, mature chickens, young turkeys, mature turkeys, ducks, geese, rabbits, and egg products (liquified eggs and dried eggs).

The goals of the NRP are as follows:

- Enforce Federal laws and regulations;
- Maintain consumer confidence by ensuring that meat, poultry, and egg products are not adulterated;
- Act as a deterrent against the slaughter of adulterated animals and the processing of adulterated eggs; and
- Assess and communicate human exposure to chemical residues.
- Provide verification of residue control in HACCP systems.

SECTION 2 COMPONENTS OF THE FSIS NATIONAL RESIDUE PROGRAM

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DOMESTIC RESIDUE SAMPLING PROGRAM

Components of the Food Safety and Inspection Service (FSIS) National Residue Program (NRP) for domestic products include Monitoring, Special Projects, Surveillance, Enforcement Testing, and the Contamination Response System. These are described below.

- Monitoring involves the sampling of specified animal populations to provide information about the occurrence of residue violations on an annual, national basis. Monitoring information is obtained through a statistically based random selection of specimens from animals that appeared normal and healthy at time of slaughter, and that have passed inspection. Generally, production classes are sampled at one of four levels (460 samples/year, 300 samples/year, 230 samples/year, or 90 samples/year). The probability of detecting a violation varies positively with the number of samples analyzed and the true violation rate of the production class being tested. The results are also used to identify producers or other entities marketing animals with violative concentrations of residues. When such producers subsequently offer animals for slaughter, the animals may be subjected to enforcement testing until compliance is demonstrated. The carcass is not retained after the sample is taken.
- **Special Projects** are information-gathering studies that do not meet the criteria for inclusion in the Monitoring Plan. When sampling will not be conducted over a full 12month period, or when there is a lack of precise slaughter volume data on the production classes to be sampled, the information that is obtained will not meet the data standards of the Monitoring Plan. Thus the Special Project designation is used. This designation is also used when it is not possible to define a "violation rate" for a compound, because the violative level has not been defined. Many chemicals, such as trace metals, industrial chemicals, and mycotoxins, may be inadvertently present in animals. Their presence in edible tissues, and the resulting need for limits to protect public health, have not been established. FSIS may conduct studies to develop information on the frequency and concentration at which such residues occur. A subset of Special Projects is Surveillance testing. Surveillance is designed to distinguish components of livestock, poultry and egg products in which residue problems exist, to measure the extent of problems, and to evaluate the impact of actions taken to reduce the occurrence of residues in the food animal population. As with the Monitoring Plan, Special Project samples (except for certain types of Surveillance samples) are taken from animals that appeared normal and healthy at the time of slaughter, and that have passed inspection.
- Enforcement Sampling/Inspector-Generated Sampling consists of the analysis of specimens obtained from individual animals or lots that appear suspicious based on herd history or ante-mortem and/or post-mortem inspection. Testing is performed to detect individual animals with violative concentrations of residues. This testing is emphasized in problem (high prevalence) populations and used as a tool to prevent residues from entering the food supply. Testing frequently results from decisions by program employees based on regional guidelines or direct observations. It is also used to follow up on producers and others who have marketed animals with violative concentrations of residues. A total of 235,495 enforcement samples was analyzed in 1996.

In-plant Tests

In-plant tests are a key part of the NRP. They provide a rapid screening method to detect the presence of residues at the plant level.

SOS, for Sulfa-On-Site, was implemented in April 1988 to test swine urine for sulfonamide residues. SOS is used in many of the largest swine slaughtering facilities. Laboratory confirmation of violations is required.

CAST, for Calf Antibiotic and Sulfonamide Test, is used to test bob veal calves (under 150 pounds and less than three weeks old). Prior to 1996, CAST did not require laboratory confirmation of the result; any violation found with CAST resulted in immediate condemnation of the calf. Beginning in 1996, any zone of inhibition measuring greater than 18 mm is sent to the laboratory for confirmation.

STOP, for Swab Test on Premises, was implemented in 1979 to detect the presence of antibiotic residues in kidney tissue. Originally developed for testing dairy cows, STOP is now used for a number of production classes. Laboratory confirmation is required before the animal carcass is condemned. Certain STOP-positive samples are tested for both antibiotics and sulfonamides; the sulfonamide violations are reported with the STOP antibiotic violations.

Confirmed STOP-positive sample specimens with sulfonamide residues that have no established limits are considered violative in those production classes for which these compounds are not approved for use.

FAST, for Fast Antimicrobial Screen Test, quickly detects both antibiotic and sulfonamide drug residues in kidneys and livers and has proved to be a suitable replacement for CAST and STOP. Though FAST is capable of detecting sulfonamides, this test is significantly less sensitive that the SOS test. FAST was implemented in pilot plants in 1995. The use of FAST has been extended to approximately 50 of the largest cow and bob veal slaughtering plants in 1996.

• Contamination Response System (CRS) is a management system to identify potential residue crises involving pesticides or other environmental contaminants, and any veterinary drugs whose occurrence requires extremely rapid response. The CRS is most commonly initiated when a residue level greater than or equal to 80% of the tolerance is detected by one of the other components of the NRP (unless otherwise defined by FSIS on an individual compound basis).

When a potential or known residue crisis is identified under the NRP, a CRS case is activated. CRS utilizes the resources of all relevant FSIS, Food and Drug Administration (FDA), Environmental Protection Agency (EPA), Animal and Plant Health Inspection Service (APHIS), and Agricultural Marketing Service (AMS) units to resolve pesticide and drug problems promptly.

IMPORT RESIDUE SAMPLING PROGRAM

The Federal Meat Inspection Act (FMIA), Poultry Products Inspection Act (PPIA), and Egg Products Inspection Act (EPIA) require foreign countries that export meat, poultry, or egg product to the U.S. to establish and maintain inspection systems that are equivalent to those of the U.S. Countries must undergo a rigorous review process before they can become eligible to export meat, poultry and egg product to the U.S. Once a country is determined to be eligible, the foreign inspection system is responsible for certifying individual establishments to FSIS. FSIS periodically reviews the inspection program of the country to ensure it remains equivalent to the U.S. system. Reinspection of product at the U.S. port-of-entry, is an additional check on the effectiveness of the foreign country's inspection system.

The principle underlying FSIS import activities is a "systems approach," which focuses on whether the foreign country's overall inspection system is equivalent to the U.S. system. FSIS does audit foreign systems to verify that the exporting country's sanitary measures achieve the U.S. inspection system's appropriate level of protection.

Residue control is a major feature of an inspection system that must be judged equivalent to the U.S. system before a country becomes eligible to export to the U.S. Foreign countries exporting to the U.S. are required to have residue control standards that lead to equivalent protection from food hazards as those of the U.S. These may include the following:

- Random sampling of animals at slaughter.
- Use of approved testing methods.
- Testing appropriate target tissues, even though such tissue may not be exported to the U.S.
- Testing for compounds identified as potential contaminants of meat exported to the U.S.
- Random sampling of eggs presented for processing

After a foreign country is determined to have an equivalent system of meat, poultry, and egg inspection and is eligible to export product to the U.S., FSIS relies on the country's national inspection authorities to certify that establishments meet all applicable standards and are authorized to export to the U.S. FSIS audits the foreign inspection system at least annually, depending on a country's performance history, including previous plant reviews and product reinspection at the port of entry. If a country does not continue to operate an inspection system equivalent to the U.S. system, including the 1996 *Final Rule on Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems*, it is removed from the official list of countries eligible to export to the U.S. published in the Federal Register.

As a further check on the effectiveness of the foreign inspection system, FSIS randomly samples meat, poultry, and egg products for reinspection at the port of entry to the U.S. Reinspection is directed by the Automated Import Information System (AIIS), which stores reinspection results from all port of entry samples for each country and for each plant. Reinspection of products is performance-based, which means that better performing foreign establishments are subject to less frequent reinspection by FSIS inspectors at official import establishments. All shipments are reinspected for transport damage, labeling, proper certification, general condition, and accurate count. The AIIS assigns a variety of types of sample inspection, which may include analysis for chemical residues. Residue analyses is not limited to those compounds included in the domestic residue program. FSIS can initiate a special sampling plan when there is a need to monitor a country for residues of a specific compound, based on detection of violative residues at port of entry, or other information concerning risk to human health. Decisions about product acceptability are based on U.S. tolerances or action levels.

Products that pass reinspection are stamped with the mark of inspection and allowed to enter U.S. commerce. If they do not meet U.S. requirements, they are stamped "U.S. Refused Entry" and must be returned to the exporting country, destroyed, or converted to animal food. In addition, the frequency of reinspection is increased for all shipments of all like product from the violative foreign establishment, until a record of compliance is reestablished.

For egg products, the first ten shipments from individual foreign establishments are subjected to 100% reinspection, to establish a history of compliance for each product category. This rate is reduced to a random selection of one reinspection out of eight shipments, which will continue as long as the product is in compliance.

SECTION 3 PLANNING THE 1999 FSIS NATIONAL RESIDUE PROGRAM: INTRODUCTION

SECTION 3. PLANNING THE 1999 FSIS NATIONAL RESIDUE PROGRAM: INTRODUCTION

BACKGROUND

The Food Safety and Inspection Service (FSIS) has focused special attention on the planning of the Monitoring Plan and Special Projects for domestic products, and upon its residue testing program for imported products, since these are the Agency's principal source of information on the occurrence of residues in meat, poultry, and egg products. The remainder of this document will explain how FSIS designed the 1999 FSIS National Residue Program (NRP) Domestic Monitoring Plan and Special Projects, and Import Residue Plan, and will provide a complete listing of the residues and production classes that are sampled under these programs.

The Domestic Monitoring Plan and Special Projects and the Import Residue Plan are public health-based residue sampling plans whose design is founded upon ideas and techniques from the field of risk assessment. It must be emphasized, however, that the results of this design process do not represent absolute estimations of risk. It was not possible for FSIS to undertake a formal risk assessment of each of the thousands of possible combinations of residues and production classes.

The design of the Monitoring Plan and Special Projects consists of four distinct phases. Phases I and II are the same for domestic and imported products, but there are some differences in Phases III and IV.

In Phase I, a comprehensive list of residues of concern in meat and poultry is generated. These residues are then ranked according to the relative public health concern presented by their potential presence in meat, poultry, and egg products. This ranking is accomplished using scoring rules that are linked to quantitative measures of hazard-relevant attributes. Only public health related criteria are used to generate and rank the list of candidate residues in Phase I. Thus the output of Phase I reflects only the relative public health concern associated with each residue, and is unaffected by any other considerations, such as laboratory resources or method availability. Criteria that must be considered in the design of a residue Monitoring Plan, yet which are not related to public health concern, are applied subsequently, in Phases II and IV. This division was made for two reasons. First, FSIS wished to know what residues were of public health concern, regardless of method or resource availability, so that, where analytical methods were not available, the Phase I ranking could be used to prioritize future FSIS method acquisition, method extension, and method development needs. Second, by starting with a list of compounds whose ranking is based purely upon relative public health concern, and by not applying other considerations (e.g., limitations on laboratory resources) until subsequent defined points within the design of the program, outside parties can more clearly understand why each residue was either selected or rejected.

In Phase II, by combing the compound rankings generated in Phase I with information on method availability and throughput, the compounds to be included in the NRP are selected. Clearly, if the FSIS laboratories do not have a method available for a compound, that compound cannot be included in the NRP. Alternately, a method may be available, but be significantly more time-consuming and inefficient than methods for other compounds. And given a choice of analyzing

for one highly ranked compound/compound class using an inefficient method, or of analyzing for two lower-ranked compounds/compound classes using more efficient methods, FSIS may choose the latter. As stated above, where FSIS cannot include a highly ranked compound in its NRP because of methodological constraints, FSIS will target such compounds for future method acquisition, extension, or development work.

In Phase III, all production classes (for domestic products) or product classes (for imported products) in which each compound or compound class may be of concern are identified. The domestic residue program ensures product safety by testing raw product immediately following slaughter. Since veterinary drug and pesticide residues are introduced into animals during production (rather than processing), FSIS ensures the safety of domestic products by testing for these residues immediately following slaughter. And since compound usage varies according to animal production class, the residue testing for the domestic program is subdivided along these lines. The production classes for which FSIS has regulatory authority include livestock, poultry, and egg products, and are listed in Table 4.6. By contrast, it is not possible to restrict testing of imported products to raw tissue, and to subdivide testing by production class. Residue testing cannot be restricted to raw tissue because some countries export processed products only. And residue testing cannot be subdivided by production class because, while countries are required to identify the animal species used in each product, they are not required to identify the production class. For example, there is no way to know if the source of a sample of ground beef was dairy cattle or beef cattle. Therefore, to obtain complete coverage of imported products, it is necessary to test both fresh and imported commodities, and to subdivide testing by animal species. The product classes tested in the import residue program are listed in Table 5.7.

In Phase IV, for domestic products, laboratory residue sampling resources were allocated among the compound/production class (C/PC) pairings identified in Phase III. For the major compound classes within the NRP, the ranking scores for each compound class are multiplied by the relative consumption figures for each production class to generate priority scores, for each of the various C/PC pairs, that parallel a public health risk assessment formula. While these priority scores do not represent estimates of risk in the absolute sense, they do provide a ranking that is consistent with the relative risk resulting from the consumption of each C/PC pair.

The priority scores were combined with historical violation rate information for each individual C/PC pair, and information on laboratory sampling capacity to select, for each pairing, from among four different sampling options: very high regulatory concern (460 analyses/year); high regulatory concern (300 analyses/year); moderate regulatory concern (230 samples/year); low regulatory concern (90 samples/year). Statistically, if the true violation rate is 1%, the probabilities of detecting at least one violation with these sampling levels are 99%, 95%, 90%, and 60% (85% at a 2% violation rate), respectively.

For imported products, in Phase IV, the risk-based ranking of the various compound/product class pairs were combined with laboratory resource information to determine residue-sampling allocations for the 1999 FSIS Import Residue Plan. Where resources were available, the ranked scores were used as a tool to select among four different sampling options for each compound/product class pair: very high regulatory concern (460 analyses/year); high regulatory

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¹An exception to this occurs with eggs, since the Food Safety and Inspection Service (FSIS) has regulatory authority for egg *products*, only, and thus conducts its residue testing upon processed, rather than fresh, eggs. Egg products consist of dried, frozen and liquid eggs. Regulatory authority for fresh eggs rests with the Food and Drug Administration (FDA).

concern (300 analyses/year); moderate regulatory concern (230 samples/year); low regulatory concern (90 samples/year). The number of samples assigned to each country was based upon the relative percent of the product class imported from each country. Each country was assigned a minimum of eight samples.

If a product class represents less than one percent (by weight) of total combined U.S. imports of meat, poultry and egg product, then the total number of samples analyzed for any compound or compound class is eight times the number of countries from which the product is imported. For example, fresh goat is imported from only two countries, and the amount imported represents 0.3% of total imports. Therefore, 16 samples of fresh goat meat would be taken for each analysis (eight from each country).

GENERATING COMPREHENSIVE LISTS OF CANDIDATE RESIDUES OF CONCERN IN MEAT, POULTRY, AND EGG PRODUCTS

Because thousands of chemicals are used worldwide and new compounds are introduced regularly, the expertise of multiple agencies is required to compile a comprehensive list of all the potential chemicals hazardous to public health that might be associated with meat, poultry, and egg products. This list should include all approved and unapproved drugs that have been known to be used or misused, and all pesticides and environmental contaminants that may be of public health concern for the domestic and import market. To adequately reflect differing risk sources, the compounds analyzed under the residue programs for domestic and imported products may not be entirely the same.

Each spring, FSIS holds meetings of the Surveillance Advisory Team (SAT) to discuss compounds of potential public health concern. SAT members include the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), the Centers for Disease Control (CDC), and several United States Department of Agriculture (USDA) agencies. The Chemistry and Toxicology Division, Office of Public Health and Science, FSIS coordinates this annual meeting.

FSIS seeks to allocate its resources in the most effective manner to ensure the safety of the U.S. food supply. Testing each animal submitted for slaughter in the U.S. for all classes of chemicals, including pesticides, animal or human drugs, and environmental contaminants, is not reasonable or practical. Once the SAT has identified the compounds of concern, the interagency Residue Prioritization Committee (RPC), meets to allocate FSIS sampling resources to the C/PC and compound/production class pairs that are of greatest public health concern. The RPC develops a statistically based residue Monitoring Plan that provides defined levels of assurance (depending upon the number of samples analyzed) of detecting residue violations in meat poultry, and egg products.

FORMAL GROUPS THAT SUPPORT THE IDENTIFICATION OF COMPOUNDS OF PUBLIC HEALTH CONCERN

SURVEILLANCE ADVISORY TEAM (SAT)

PURPOSE

The SAT participants identify:

- The "universe" of compounds,
- Specific residues of public health concern,
- Analytical residue method development needs
- Emerging issues for chemical hazards

CHAIR

 Director, Chemistry and Toxicology Division, Office of Public Health and Science (OPHS), FSIS, USDA

PARTICIPANTS

- Health Effects Division, Office of Pesticides, Prevention, and Toxic Substances, EPA
- Center for Food Safety and Applied Nutrition, FDA, Department of Health and Human Services (HHS)
- Center for Veterinary Medicine, FDA, HHS
- Centers for Disease Control and Prevention, HHS
- Animal and Plant Health Inspection Service, USDA
- Science and Technology, Agricultural Marketing Service, USDA
- Agricultural Research Service, USDA
- Chemistry and Toxicology Division, OPHS, FSIS, USDA
- Microbiology Division, OPHS, FSIS, USDA
- Epidemiology and Risk Assessment Division, OPHS, FSIS, USDA
- Scientific Research Oversight Staff, OPHS, FSIS, USDA
- Food Hazard Surveillance Division, OPHS, FSIS, USDA
- Emergency Response Division, OPHS, FSIS, USDA
- Field Service Laboratories, OPHS, FSIS, USDA
- Technical Service Center, Office of Field Operations (OFO), FSIS, USDA
- Federal-State Relations Staff, OFO, FSIS, USDA
- Animal Production Food Safety Program, Office of Policy, Program Development and Evaluation (OPPDE), FSIS, USDA
- Domestic Policy Development and Evaluation Division, OPPDE, FSIS, USDA
- International Policy Division, OPPDE, FSIS, USDA
- Inspection Systems Development Division, OPPDE, FSIS, USDA

B. RESIDUE PRIORITIZATION COMMITTEE (RPC)

PURPOSE

The RPC evaluates the compounds identified by the SAT, ranks them *according to their relative public health concern*, and works with the FSIS Field Service Laboratories to finalize the domestic Monitoring Plan and Special Projects and the Import Residue Plan

CHAIR

• Emerging Issues Branch, Chemistry and Toxicology Division, OPHS, FSIS, USDA

PARTICIPANTS

- Health Effects Division, Office of Pesticides, Prevention, and Toxic Substances, EPA
- Center for Food Safety and Applied Nutrition, FDA, HHS
- Center for Veterinary Medicine, FDA, HHS
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